**HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL) – SUB-STUDY APPLICATION FORM 2025**

**FOR DEGREE AND OTHER INVESTIGATOR INITIATED RESEARCH**

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| **When is a sub-study application appropriate?** It is appropriate in a case wherein the applicant is interpreting data already collected under an earlier ethics clearance. Evidence is required that the person who was awarded the earlier clearance has agreed to grant access to their data for the purposes of a sub-study. If the applicant is gathering new data, interviewing participants, examining new samples, etc., this does not meet the HREC (Med) definition of a sub-study and a full application is required. Sub-studies satisfying this criterion may be submitted, by e-mail (HREC-Medical.ResearchOffice@wits.ac.za), to the Medical Ethics Office at any time, *i.e.* they are not subject to the published monthly closing dates for full applications. |

**IMPORTANT INSTRUCTIONS:**

* Read all the Appendices before completing this application form. Answer all questions (Y/N), incomplete application will not be accepted. State N/A rather than leaving question blank.
* **Please check the appropriate checkbox using an ‘X’**. This application form **must be typed**, handwritten form will not be accepted.

**SECTION 1 – SUB-STUDY DETAILS:**

**1.1 Purpose of the Research:**

Postgraduate Degree/Diploma: **Yes [ ]  No [ ]**  (state which):

Undergraduate Degree/Diploma: **Yes [ ]  No [ ]**  (state which):

Not for Degree Purposes: **Yes [ ]  No [ ]**

**1.2** Is this a New Submission? **Yes [ ]  No [ ]**

**1.3** Is this a Resubmission? **Yes [ ]  No [ ]**

(**If yes**, please give the initial HREC number):

**1.4**  **Details of Original/Primary Study:**

Study Title:

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HREC approval number:

Principal Investigator:

**SECTION 2 – SUB-STUDY TITLE IN FULL** (No abbreviations)**:**

|  |
| --- |
| **Study Title**:  |

**SECTION 3 – INVESTIGATOR(S)/ SUPERVISOR(S)/APPLICANT INFORMATION:**

**3.1 PRINCIPAL INVESTIGATOR(S):**

|  |  |
| --- | --- |
| **TITLE** (Prof/Dr/Mr/Mrs/Miss/Ms/Other): |  |
| **FIRST NAME** |  |
| **SURNAME** |  |
| **TELEPHONE**/**CELL NO** |  |
| **E-MAIL** |  |
| **WITS STAFF/STUDENT NUMBER** |  |
| **PROFESSIONAL STATUS, OR STUDENT YEAR OF STUDY AND DEGREE** |  |
| **DEPARTMENT/DIVISION/RESEARCH ENTITY:** |  |
| **SITES(S) WHERE THE RESEARCH WILL BE CARRIED OUT (**Please furnish hospital/institution and department**)** |  |
| **NAME AND DATE OF ETHICS TRAINING**(Please include/attach certificate) |  |

**3.2 SUPERVISOR(S) DETAILS:**

|  |  |
| --- | --- |
| **TITLE** (Prof/Dr/Mr/Mrs/Miss/Ms/Other): |  |
| **FIRST NAME** |  |
| **SURNAME** |  |
| **TELEPHONE**/**CELL NO** |  |
| **E-MAIL** |  |
| **DEPARTMENT/DIVISION/RESEARCH ENTITY:** |  |
| **NAME AND DATE OF ETHICS TRAINING**(Please include/attach certificate) |  |

**3.3 APPLICANT DETAILS** (if applicable – applying on behalf of PI/Investigators):

|  |  |
| --- | --- |
| **TITLE** (Prof/Dr/Mr/Mrs/Miss/Ms/Other): |  |
| **FIRST NAME** |  |
| **SURNAME** |  |
| **TELEPHONE**/**CELL NO** |  |
| **E-MAIL** |  |
| **DEPARTMENT/DIVISION/RESEARCH ENTITY:** |  |
| **NAME AND DATE OF ETHICS TRAINING**(please include/attach certificate) |  |

**SECTION 4: SUB STUDY DETAILS** (please avoid copying and pasting from the study protocol)**:**

**4.1 Objectives and end points of the research** (plain language):

Primary (if applicable):

Secondary (if applicable):

Other:

**4.2 Brief sub study background** (e.g., disease, procedures, medicines, etc.):

**4.3 Brief summary of the research:** (give a brief outline of the research plan such that reviewers can understand what is to be done). (*Do not say “see attached”*):

* + 1. **Sub study Design and Methodology:**

Summary:

* + 1. **Duration of sub study:**

Start Date: **(DD/MM/YYYY)** \*must be after HREC (Medical) meeting/approval.

Stop Date: **(DD/MM/YYYY)**

* + 1. **Please give a brief Summary of Inclusion and Exclusion Criteria (important ones only):**

## Indicate which study design(s) will be used. Mark/check all appropriate blocks with an “X”

 **[ ]** Qualitative Lab based **[ ]**

 **[ ]** Quantitative AI / Computer based **[ ]**

 **[ ]** Cross-sectional Health Economics **[ ]**

 **[ ]** Observational/Epidemiological Other (please describe briefly below)  **[ ]**

If you selected other, please describe the methodology

**SECTION 5: GENERAL INFORMATION\***

##  5.1 Access to the results \*

 To whom will the results be made available, e.g., participants, supervisor, hospital management, etc.?

##  5.2 Dissemination of results \*

## How will the results and findings be disseminated? (E.g., peer reviewed journal article, conference proceeding, departmental seminar, etc.)

##  5.3 Other helpful information.

 Provide additional information that may be used by the HREC (Med) to evaluate this case report

 application.

##  5.4 Ethics training. \*

 Please see the Guiding Information in the Appendix related to ethics training.

 Note: It is essential to attach evidence of suitable training completed within the previous 3 years.

**SECTION 6: INFORMATION, DECLARATION AND SIGNATURES (To be kept on separate page) \***

**Investigator(s) Name and Surname:**

In appending my signature below, I confirm that am aware of and agree to abide by the University’s policy on plagiarism, as referenced in Appendix 3 to this Application Form.

I have read and understood the terms and conditions in Appendix 3 of the HREC (Medical) Application Form. I acknowledge that it is my responsibility to ensure that I have received final HREC (Medical) clearance before commencing any research.

I declare that I have not and will not collect data or do secondary data analysis, or any other form of research involving human participants, prior to obtaining a Clearance Certificate from the HREC (Medical).

|  |
| --- |
| **Repeat Sub study Title here:**  |

**PRINCIPAL INVESTIGATOR(S):**

|  |  |
| --- | --- |
| *Name:* *Please Print Title, Name and Surname*  |  |
| *Department:*  |  |
| **Email:** |  |
| **Date:** |  |
| **Signature:** |  |

**APPLICANT (where applicable -** applying on behalf of PI/Investigators**):**

|  |  |
| --- | --- |
| *Name:* *Please Print Title, Name and Surname*  |  |
| *Department:*  |  |
| **Email:** |  |
| **Date** |  |
| **Signature:** |  |

 **SUPERVISOR(S) (where applicable):**

|  |  |
| --- | --- |
| *Name:* *Please Print Title, Name and Surname* |  |
| *Department:*  |  |
| **Email:** |  |
| **Date** |  |
| **Signature:** |  |

 **HEAD OF DEPARTMENT / UNIT OF INSTITUTION / RESEARCH ENTITY IN WHICH STUDY WILL**

 **BE CONDUCTED:**

|  |  |
| --- | --- |
| **Name:***Please Print Title, Name and Surname* |  |
| **Head of Dept / Unit of Institution / Research Entity where study will be conducted:** |  |
| **Date:** |  |
| **Signature:** |  |

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| **PLEASE DO NOT SUBMIT THE APPENDICES WITH YOUR APPLICATION FORM, IT IS FOR YOUR INFORMATION.** |

**APPENDIX 1 - SUBMISSION REQUIREMENTS FOR A SUB-STUDY**

**1. REQUIRED UPFRONT FOR A SUB STUDY APPLICATION TO BE ACCEPTED:**

 **ANY INADEQUATE SUBMISSION WILL BE REJECTED**

1. Completed and signed Sub-study **Application Form**.
* All sections must be completed correctly.
* Realistic duration of study (section 4.3.2) – usually start date should be 6 weeks or more after scheduled HREC (Medical) meeting date.
* Section 9 must be signed by PI, Supervisor(s) and Academic HoD.
* Degree and non-degree studies must be signed by PI and HoD other than PI, if PI is HoD. This includes Wits affiliates i.e. academic staff, entities, public government institution and NGOs affiliated with Wits.
1. Clean **Sub Study Research Proposal/Protocol**. Compulsory for all applications/submissions (non-degree, undergraduate and postgraduate degree).
2. **Ethics training certificates** for all investigators and supervisors (not >3 years old); GCP training is not sufficient.
3. Data extraction sheet (no identifiers).
4. Faculty protocol approval letter, where the study is for the purposes of a postgraduate degree
5. Participant Consent Sheet from the original study (not the Information Sheet).
6. Letter from the Principal Investigator on the original study granting access to his or her data to the sub-study applicant.
7. Anything else as appropriate.

**Ethics training**

Ethics training is a compulsory requirement for consideration of this application. This applies to the applicant, any co-applicants and the supervisor(s), where there is one (or more). If you do not already have ethics training, one easy way to get it is to go to <https://elearning.trree.org/course/index.php?categoryid=1> and complete at least the Introductory Module, which costs nothing and will generate a certificate. Please attach copies.

National HREC rules stipulate that ethics training certificates are not acceptable if they are more than three years old and that Good Clinical Practice Certificates are only acceptable in this context if they specify an ethics component.

**NB: NOTE: STUDY SITES WITH INSUFFICIENT DOCUMENTATION MAY BE REJECTED WITHOUT AFFECTING THE APPROVALS OF OTHER SITES**.

**Note Well: no data may be collected before the issue of an ethics clearance. In no circumstance will ethics clearance be issued retrospectively.**

**APPENDIX 2 – LIST OF POSSIBLE APPROVALS AND DOCUMENTS (if applicable):**

1. **SAHPRA.**
2. **University Protocol Review Committee or Postgrad Approval Letter.**
3. **University Registrar/School authority.**
4. **Research Ethics Training Certificate for all Investigators and Supervisors (not more than three years old) and GCP Training Certificate** (if applicable).
5. **Gatekeeper or database keeper permission for secondary data analysis** (plus a list of the data to be recorded must accompany this application; omit all identifiers on the data collection sheet – name, address, contact details, date of birth, etc.; use a study number to identify individuals where necessary).
6. **South African National Clinical Trials Registry (SANCTR).**
7. **National Health Research Database (NHRD) registration.**
8. **NHLS approval for access to Bio samples: AARMS registration.**
9. **Hospital CEO or Representative.**
10. **HoD.**
11. **District Manager.**
12. **Provincial or National Department of Health**
13. **Other Independent Ethics Committees/Institutional Review Board (IRBs).**

**APPENDIX 3 - RESPONSIBILITIES:**

1. Please note that it is the responsibility of the Principal Investigator and the Supervisor (if applicable) in an application to ensure that he/she has received the final HREC (Medical) Clearance before commending any research. This is signified by, and only by, the issuing of a Clearance Certificate, which will be headed as such.
2. Please indicate clearly, where correspondence should be sent; failure to do this may cause delays. Please provide the PI and the supervisor’s email address (where applicable) for sending copies of correspondence.
3. Please provide a protocol detailing the background to the research, the design of the investigation and all procedures, is submitted with the application.
4. Researchers with syndicates in the Wits Health Consortium – please read the home page at [www.witshealth.co.za](http://www.witshealth.co.za) regarding the requirement that the syndicate must be based in a Wits academic department, or recognised research entity.
5. Please note: No late online applications will be accepted after the submission date listed at: <https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/>, chose HREC (Med), see “Downloads”. Applications received after this date will be carried forward to the following meeting: incomplete applications will not be accepted.
6. For any assistance, please contact the WRO Ethics Secretariat to the Human Research Ethics Committee (Medical) at 011 717 2700/1234/2656 or email: Hrec-Medical.ResearchOffice@wits.ac.za
7. No data may be collected before ethics clearance certificate is issued by the HREC (Medical). In no circumstance will retrospective clearance be given.

**WITS PLAGIARISM POLICY:**

1. The University’s policy on plagiarism is set out at: <https://intranet.wits.ac.za/exec/registrar/Policies/Policy%20%20Plagiarism.pdf#search=plagiarism>
2. Applicants seeking ethics clearance are required to be familiar with this policy.

# HREC (Medical) Committee Form Revision/Edit version Number

* Application Form version 02, 11 Dec 2024.